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and Debtors in Possession*

**UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK**

In re:

**PURDUE PHARMA L.P., et al.,

Debtors.¹**

Chapter 11

**Case No. 19-23649 (RDD)

(Jointly Administered)**

**NOTICE OF FILING OF
AMENDED AND RESTATED FUNDING AGREEMENT**

PLEASE TAKE NOTICE that on March 2, 2022, the above-captioned debtors and debtors in possession (collectively, the “**Debtors**”) filed the *Motion of Debtors for Authorization to Enter into Amended and Restated Funding Agreement* (the “**Motion**”)² [ECF No. 4407], seeking entry of an order authorizing the Debtors to enter into and perform under an amended and restated

¹ The Debtors in these cases, along with the last four digits of each Debtor’s registration number in the applicable jurisdiction, are as follows: Purdue Pharma L.P. (7484), Purdue Pharma Inc. (7486), Purdue Transdermal Technologies L.P. (1868), Purdue Pharma Manufacturing L.P. (3821), Purdue Pharmaceuticals L.P. (0034), Imbrium Therapeutics L.P. (8810), Adlon Therapeutics L.P. (6745), Greenfield BioVentures L.P. (6150), Seven Seas Hill Corp. (4591), Ophir Green Corp. (4594), Purdue Pharma of Puerto Rico (3925), Avrio Health L.P. (4140), Purdue Pharmaceutical Products L.P. (3902), Purdue Neuroscience Company (4712), Nayatt Cove Lifescience Inc. (7805), Button Land L.P. (7502), Rhodes Associates L.P. (N/A), Paul Land Inc. (7425), Quidnick Land L.P. (7584), Rhodes Pharmaceuticals L.P. (6166), Rhodes Technologies (7143), UDF LP (0495), SVC Pharma LP (5717) and SVC Pharma Inc. (4014). The Debtors’ corporate headquarters is located at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

² Capitalized terms used but not defined herein shall have the meaning ascribed to such terms in the Motion.

funding agreement (the “**A&R Agreement**”) by and between PPLP and Harm Reduction Therapeutics, Inc. (“**HRT**”), substantially in the form attached thereto as **Exhibit B**.

PLEASE TAKE FURTHER NOTICE that a revised, final form of A&R Agreement is attached as **Exhibit A** to this notice. A blackline showing changes between the original form of A&R Agreement as filed with the Motion and the revised, final form of A&R Agreement is attached as **Exhibit B** to this notice.

PLEASE TAKE FURTHER NOTICE that copies of the Motion, including the final form of A&R Agreement, may be obtained free of charge by visiting the website of Prime Clerk LLC at <https://restructuring.primeclerk.com/purduepharma>. You may also obtain copies of any pleadings by visiting the Bankruptcy Court’s website at <http://www.nysb.uscourts.gov> in accordance with the procedures and fees set forth therein.

Dated: March 23, 2022
New York, New York

DAVIS POLK & WARDWELL LLP

By: /s/ Eli J. Vonnegut

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*Counsel to the Debtors
and Debtors in Possession*

Exhibit A

Revised Form of Amended and Restated Funding Agreement (Execution Copy)

AMENDED AND RESTATED FUNDING AGREEMENT

This Amended and Restated Funding Agreement (“Agreement”) is dated as of March 22 , 2022 between Harm Reduction Therapeutics, Inc., a nonstock Maryland not-for-profit corporation (“HRT”), and Purdue Pharma L.P., a Delaware limited partnership (“PPLP”). (As used herein, each of HRT and PPLP is referred to as a “Party” and collectively as the “Parties.”)

WHEREAS, the Parties previously entered into a Funding Agreement, dated as of June 25, 2020 (“Funding Agreement”);

WHEREAS, PPLP has provided funding to HRT, under the Funding Agreement, in the amount of \$6,500,000 based on HRT’s achievement of certain milestones set forth in the Funding Agreement;

WHEREAS, the Parties wish to amend and restate the Funding Agreement in its entirety;

WHEREAS, in addition to the funding provided under the Funding Agreement, PPLP has previously provided HRT funding to begin development of the Product including pursuant to prior written agreements between the Parties (the “Prior Agreements”);

WHEREAS, this Agreement is intended to supersede all Prior Agreements between the Parties, other than the Letter Agreement dated November 9, 2017 (the “Confidentiality Agreement”) and the Agreement dated as of July 29, 2019 (the “Right of Reference Agreement”);

WHEREAS, PPLP is committed to addressing opioid use disorder and is seeking partners to support and accelerate impactful initiatives and scientific discoveries;

WHEREAS, HRT is interested in developing, marketing, seeking Regulatory Approval of, and distributing solely in the Territory a single dose, over-the-counter, naloxone intranasal spray device intended to treat opioid overdoses (the “Product”);

WHEREAS, PPLP and HRT wish to enter into this Agreement pursuant to which PPLP will fund the continuation of HRT’s development work in connection with the Product with the goal of having HRT seek Regulatory Approval of the Product and ultimately for HRT to be able to provide the approved Product to first responders, government agencies, not-for-profit entities, communities and individuals (collectively, “Contemplated Product Users”), subject to the terms and conditions set forth below.

NOW THEREFORE, HRT and PPLP, intending to be legally bound, hereby agree as follows:

ARTICLE I DEFINITIONS

- 1.1 “Approval Order” means an order of the Bankruptcy Court, in form and substance reasonably acceptable to the Parties, approving PPLP’s entry into this Agreement.

- 1.2 “Bankruptcy Court” means the United States Bankruptcy Court for the Southern District of New York having jurisdiction over the Chapter 11 Cases.
- 1.3 “Chapter 11 Cases” means the bankruptcy cases filed on September 15, 2019 by PPLP and certain of its affiliates under Chapter 11 of the United States Code in the Bankruptcy Court and jointly administered under Case No. 19-23649 (RDD).
- 1.4 “Claim” means, with respect to any Person, any claim, demand, action, proceeding, judgment, damage, loss, cost, expense, or liability whatever, incurred or suffered by or brought, made, or recovered against such Person (whether or not presently ascertained, immediate, future, or contingent) arising out of or relating to the sale or use of the Product by HRT or by any holder or user of the Product that in the chain of distribution came from or through HRT.
- 1.5 “Cost” means HRT’s cost of goods sold for PPLP Funded Products (as defined in Section 2.3), on a fully absorbed basis, including general and administrative expenses, in accordance with United States generally accepted accounting principles, and any federal excise taxes and other federal, state and local taxes, as applicable.
- 1.6 “FDA” means the United States Food and Drug Administration, or any successor entity.
- 1.7 “GMP” means the then-current good manufacturing practices set forth in the quality system regulation 21 C. F. R. Part 820, governing the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use, as such practices may be updated from time to time.
- 1.8 “IND” means an Investigational New Drug Application as defined in the Federal Food, Drug and Cosmetic Act (“FD&C Act”).
- 1.9 “Milestone Event” means any of the events set forth in Section 2.2 under the column “Milestone Event.”
- 1.10 “Milestone Payment” means any of the payments set forth in Section 2.2 under the column “Milestone Payment.”
- 1.11 “NDA” means a New Drug Application as defined in the FD&C Act.
- 1.12 “Original Effective Date” means the effective date of the Funding Agreement.
- 1.13 “Person” means any natural person, corporation (including any non-profit corporation), cooperative, company, foundation, general partnership, limited partnership, limited liability company, unlimited liability company, joint venture, estate, trust, association, organization, labor union, governmental body, custodian, nominee and any other individual or entity.

- 1.14 “Product Registration” means, in relation to the Product, an NDA that has been approved by the FDA, including any amendments or supplements.
- 1.15 “Regulatory Approval” means drug approval and all other approvals necessary for the distribution of Product in the Territory.
- 1.16 “Regulatory Authority” means any federal, state, local, municipal, provincial or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).
- 1.17 “Regulatory Materials” means regulatory applications, submissions, notifications, communications, correspondence, registrations, drug approvals or other filings made to, received from or otherwise conducted with a Regulatory Authority to develop, manufacture, market, sell or otherwise distribute Product in the Territory.
- 1.18 “RiVive” means the proposed name of 3.0 mg of the intranasal Product (as such name may be amended from time to time).
- 1.19 “Territory” means the United States of America, including its territories and possessions.
- 1.20 “Unit” means one package containing two RiVive intranasal naloxone devices.

ARTICLE II EFFECTIVENESS; FINANCIAL ASSISTANCE

- 2.1 **Effectiveness.** This Agreement shall, upon entry of the Approval Order by the Bankruptcy Court and execution and delivery by the Parties, become effective and binding upon the Parties (such date, the “Amended and Restated Effective Date”).
- 2.2 **Financial Assistance; Milestone Payments.**
- (a) HRT will use commercially reasonable efforts to develop the Product and will use the funding provided by PPLP and referenced below only for (i) the development of the Product, (ii) other related activities, and (iii) general working capital, including legal and compliance costs and expenses.
- (b) PPLP hereby agrees to provide funding to HRT in the form of Milestone Payments to encourage HRT’s continued development of the Product in the Territory, payable after the achievement of certain Milestone Events. The Milestone Payments are described below:

Milestone Event and Primary Purpose	Milestone Payment	Expected Milestone Achievement/ Expected Payment Date
Clinical study successfully demonstrates that RiVive naloxone	\$3,000,000	Completion date: January 31, 2022. Milestone achieved.

concentrations are as high as the FDA approved comparator product (Development, drug product stability, NDA preparation, device reliability and production equipment)		Payment Due Date: April 1, 2022
Acceptable drug product 24-month stability achieved to support targeted 24-month shelf life for commercial product (NDA preparation, pre-validation batch manufacture, sales & marketing preparations and on-going development work)	\$3,000,000	Targeted completion date: August 31, 2022 Payment Due Date: Within thirty (30) days after HRT delivers a written notice to PPLP that the applicable milestone has been met
New Drug Application for RiVive filed with the FDA (Manufacturing site readiness, partial support of commercial batch components, sales and marketing support prior to 1 st commercial shipment)	\$5,000,000	Targeted completion date: October 28 th , 2022 Payment Due Date: Within thirty (30) days after HRT delivers a written notice to PPLP that the applicable milestone has been met

The above referenced milestone achievement dates are expected dates only, are not intended to be deadlines and do not trigger any Milestone Payments (unless the Milestone Event has actually occurred). Each Milestone Payment is a one-time only payment based on the achievement of the Milestone Event; provided, that no Milestone Payment will be made unless the previously listed Milestone Event has been achieved. Promptly after HRT determines that it has achieved a Milestone Event, HRT shall provide notice thereof to PPLP in accordance with Section 9.2 hereof, which notice shall include sufficient detail of the achievement of such Milestone Event to enable PPLP to verify whether it agrees with HRT's determination. If, after receipt of the foregoing notice, PPLP agrees, reasonably and in good faith, that a Milestone Event has been achieved by HRT, PPLP shall pay the corresponding Milestone Payment to HRT within the time period set forth in the above chart after the date the Milestone Event was achieved or at such later time as HRT may request; provided, in no event will the Milestone Payment be due prior to the corresponding expected Payment Date set forth in the above chart. If PPLP does not agree that a Milestone Event has been achieved, the Parties will work in good faith to resolve any such dispute.

The aggregate amount of the Milestone Payments shall not exceed eleven million dollars (\$11,000,000). Any amounts not funded in 2022 will be funded in the subsequent year; provided, that PPLP shall in no event be required to fund any amounts after March 31, 2023, regardless of whether a Milestone Event is achieved after such date.

Notwithstanding the foregoing, (i) if HRT licenses from a third party an FDA-approved product (i.e., with a Regulatory Approval) to serve as the Product, PPLP shall not make

the Milestone Payments referred to above, but the Parties will discuss in good faith any alternative funding that may be required by HRT to obtain approval for the Product (i.e., with a Regulatory Approval) to be distributed over-the-counter and (ii) if HRT receives any funding from any third party that is based on a new request or application made or submitted solely after the Original Effective Date to fund the development of the Product pre-commercialization, and such third party financing is received, such third party funding will reduce the amount of subsequent unpaid Milestone Payments by the amount of such third party funding (with the understanding that it will not reduce any other Milestone Payment hereunder and that HRT will have no obligation to return any Milestone Payments previously paid to HRT).

2.3 **Financial Assistance for HRT's Manufacture and Distribution of Product.**

As part of PPLP's public health initiatives, after FDA Regulatory Approval of HRT's NDA for the Product, PPLP may provide funds to HRT to enable HRT to manufacture Units of Product ("PPLP Funded Products") so that such Units can be donated free of charge or sold at Cost to Contemplated Product Users. The current market forecast for at Cost Units is depicted on Exhibit A attached hereto.

In the event PPLP does provide funding to HRT to enable HRT to manufacture PPLP Funded Products, at least two (2) months prior to each calendar quarter HRT and PPLP will agree upon a written annual forecast of PPLP Funded Products to be manufactured and donated free of charge or sold at Cost to the Contemplated Product Users as follows:

(i) a binding forecast for the quantities of PPLP Funded Products to be manufactured and donated free of charge or sold at Cost to the Contemplated Product Users during the upcoming calendar quarter, with projected delivery dates, sizes, strengths and ultimate destinations, as well as other relevant manufacturing and delivery information. PPLP shall fund one hundred percent (100%) of the Cost of such agreed upon forecast of PPLP Funded Products;

(ii) an estimate of the quantities of PPLP Funded Products to be manufactured and donated free of charge or sold at Cost to the Contemplated Product Users during the calendar quarter following the upcoming calendar quarter. PPLP shall fund at least fifty percent (50%) of the Cost of such forecast of PPLP Funded Products; and

(iii) a non-binding estimate of the forecast of PPLP Funded Products HRT intends to manufacture and which will be donated free of charge or sold at Cost to the Contemplated Product Users for the third and fourth calendar quarters of such forecast.

Each subsequent written forecast shall update the prior estimate and include an estimate of requirements for the next additional calendar quarter, so that estimates for a rolling one- (1-) year period are provided.

For avoidance of doubt, HRT shall not be obligated to produce and deliver any PPLP Funded Product to any Contemplated Product User unless PPLP has funded the applicable verifiable Cost related thereto, sufficient time in advance, as agreed upon by

the Parties, in accordance with the forecasts set forth above or otherwise (at an agreed upon rate reasonably calculated to allow HRT to diligently produce the Product). Any payments received by HRT in advance of the future donation or sale of PPLP Funded Products will be credited to the funding of the next forecasted quantities of PPLP Funded Products. Following the filing of an NDA for the Product, PPLP and HRT may further refine the forecasting provisions set forth above.

2.4 **Audit Rights.**

- (a) Commencing as of the Original Effective Date and ending on the earlier of (i) termination or expiration of this Agreement, or (ii) the third anniversary of the latest delivered Milestone Payment, PPLP shall have the right to conduct audits of HRT's data and its books and records to reasonably determine whether Milestone Events have been achieved.
- (b) Commencing as of the Original Effective Date, PPLP shall have the right to conduct audits of the books and records of HRT not more than once during each calendar year (i) until the date of Regulatory Approval of HRT's NDA for the Product, to determine that the funds provided by PPLP have been used in a manner consistent with Section 2.2 (a) and (ii) after FDA Regulatory Approval of HRT's NDA for the Product and until the termination of this Agreement, to verify HRT's Cost related to Units of Product.
- (c) PPLP may exercise the audit rights described in (a) and (b) above by providing written notice to HRT and any such audit shall be conducted during normal business hours. HRT shall make available to PPLP such accounting and other books and records, reasonably requested by PPLP to exercise its rights hereunder.

2.5 **Reports.**

At least once during each month until the last Milestone Event has been achieved, HRT shall provide a written report to PPLP regarding its progress toward developing the Product and achieving the Milestone Events, including an update on the Expected Milestone Achievement Date for each such Milestone Event. Each report will account for HRT's expenditures of funding provided by PPLP allocated among the three categories set forth in Section 2.2(a). HRT shall also report on any funding that it received from third parties in connection with the Product, promptly after it becomes aware of such funding.

ARTICLE III INTELLECTUAL PROPERTY

- 3.1 **Ownership of Data; Product Registrations.** HRT will be the sole owner of (a) all the data generated by HRT supporting development and registration of the Product, (b) the database of such data, (c) all Regulatory Approvals and Product Registrations in the

Territory, and (d) all Regulatory Materials, except as may be set forth in any other agreement between the Parties.

- 3.2 **IP Assignment.** HRT and its affiliates may assign, sell, license or otherwise transfer any intellectual property related to the Product, only with the prior written consent of PPLP, such consent not to be unreasonably withheld or denied. Any purported assignment, sale or transfer of rights in or to any intellectual property in contravention of this Section 3.2 shall be null and void ab initio. The restrictions set forth in this Section 3.2 shall expire on June 30, 2039. PPLP hereby consents to the grant, by HRT, of a non-exclusive license to the Producer (as defined below) related to the underlying intellectual property of the Product, for the limited purpose of producing, manufacturing and supplying the Products for HRT. "Producer" means HRT's currently contemplated producer, contract manufacturer and supplier of the Products, and any substitutes (in whole or in part) thereof.

ARTICLE IV REPRESENTATIONS, WARRANTIES AND COVENANTS

- 4.1 **Mutual Representations and Warranties.** Each Party hereby represents and warrants to the other Party as of the date hereof and as of the Original Effective Date and Amended and Restated Effective Date as follows:
- A. **Authority.** It is validly existing and in good standing or active under the laws of the jurisdiction of incorporation or organization, has the power and authority to enter into this Agreement and has taken all necessary actions on its part required to authorize the execution and delivery of this Agreement. This Agreement has been duly executed and delivered by such Party and constitutes the valid and binding obligation of such Party, enforceable against it in accordance with its terms except as enforceability may be limited by bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to or affecting creditors' rights generally and by general equitable principles. The execution, delivery and performance of this Agreement has been duly authorized by all necessary action on the part of such Party, its officers, directors, members and/or managers, as applicable.
- B. **No Conflict.** The execution, delivery and performance of this Agreement by such Party does not, to such Party's knowledge, violate any material law or regulation or any order of any court, governmental body or administrative or other agency having authority over them. It is not currently a party to any material agreements, oral or written, that would cause it to be in breach of its obligations under this Agreement, and execution and delivery of this Agreement does not and will not conflict with, violate or breach any contractual obligations of such Party.
- 4.2 **HRT Representations, Warranties and Covenants.** HRT hereby further represents, warrants and covenants to PPLP that:

- A. As of the Original Effective Date, HRT is and, during the term of this Agreement will continue to be, a nonstock corporation organized under the laws of the State of Maryland. HRT shall not contemplate pecuniary gain or profit, incidental or otherwise, and no part of the net earnings of HRT shall inure to the benefit of or be distributed to any director or officer of HRT, or to any other private person, except that HRT shall be authorized and empowered to pay reasonable compensation for services rendered and to make payments and distributions in furtherance of its charitable and/or public benefit purposes.
- B. While receiving funding from PPLP under this Agreement, HRT will not participate in any lobbying activities that are prohibited by PPLP injunction(s), as delivered to HRT in writing from time to time. Advocacy by HRT before any Regulatory Authority regarding Regulatory Approval of the Product shall not be deemed to violate this Section 4.2(B).
- C. HRT will develop the Product, manufacture PPLP Funded Products, and sell or donate PPLP Funded Products, in compliance with all applicable laws, including any applicable state transparency laws and applicable guidelines such as GMP (as and to the extent applicable to the PPLP Funded Products), then-current good clinical practice standards and procedures promulgated or endorsed by the FDA (as and to the extent applicable), then-current good laboratory practice standards promulgated or endorsed by the FDA and guidelines issued by the International Council for Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (as and to the extent applicable).
- D. HRT will use commercially reasonable efforts (taking into account the applicable global and local economic, health/pandemic and market conditions, as well as availability of funding) to obtain funding from third parties for the development of the Product and to supply funding for supply readiness and launch of the Product.
- E. If HRT is no longer organized for charitable or public benefit purposes or no longer otherwise qualifies as any of (i) a non-stock corporation, (ii) a benefit corporation, or (iii) another form of entity acceptable to PPLP, (x) HRT will provide written notice to PPLP that it is no longer so organized or no longer so qualifies, (y) HRT will repay to PPLP all amounts provided to it by PPLP under this Agreement, including all cash funding provided by PPLP to HRT under the Prior Agreements, no later than one (1) year after written request for such repayment is made by PPLP and (z) in PPLP's sole discretion but subject to HRT's receipt of any necessary governmental or regulatory approvals and compliance with applicable laws, PPLP will be entitled to forty percent (40%) of all of the equity interests in HRT. For clarity, denial of HRT's application for treatment as a tax exempt entity under Section 501(c)(3) of the Internal Revenue Code of 1986, as amended, by itself, will not mean that HRT no longer qualifies as an entity described above.

ARTICLE V
TERM AND TERMINATION

- 5.1 **Term.** This Agreement shall become effective on the Amended and Restated Effective Date and shall remain in effect until terminated pursuant to Sections 5.2, 5.3 or 5.4.
- 5.2 **Termination for Material Breach.** Either Party shall have the right to terminate this Agreement in the event that the other Party commits a material breach of this Agreement by giving written notice of such breach to the breaching Party. Termination shall be effective ninety (90) days after the giving of such notice unless the breaching Party has remedied the breach within such ninety (90) day period.
- 5.3 **Termination for Bankruptcy or Change of Status.** PPLP may terminate this Agreement upon notice to HRT if HRT becomes insolvent, makes any assignment for the benefit of its creditors, is placed in receivership, liquidation or bankruptcy or if it is no longer organized for charitable, or public benefit purposes or no longer otherwise qualifies as any of (i) a non-stock corporation, (ii) a benefit corporation, or (iii) another form of entity acceptable to PPLP. PPLP's right to terminate under this Section 5.3 is in addition to any of its rights under Section 4.2 E. of this Agreement.
- 5.4 **Termination by PPLP.** PPLP may terminate this Agreement, upon (x) fifteen (15) days' prior written notice if HRT has not achieved a Milestone Event set forth in Section 2.2 within one hundred eighty (180) days of the Targeted Completion Date set forth with respect to such Milestone Event or (y) sixty (60) days' prior written notice, if HRT has stopped using commercially reasonable efforts to develop Product in the Territory (during which sixty (60)-day period HRT may resume using such efforts and upon PPLP's reasonable satisfaction that such efforts have resumed such notice shall be withdrawn).
- 5.5 **Publicity Upon Termination.** If either Party terminates this Agreement for any reason, the Parties will agree upon the wording of any public announcement of such termination and, if the Parties are unable to reach such agreement, neither Party shall release any public announcement relating to such termination without the other Party's written consent. Following any termination of this Agreement, HRT will not make any public statements about this Agreement, the circumstances surrounding the termination or the relationship between the Parties without the prior written consent of PPLP, except for any such statements required pursuant to legal process. PPLP will give HRT prior written notice of any statement it proposes to make following such termination and, except for statements made pursuant to legal process, will take into consideration any comments HRT may have with respect to such statements. Notwithstanding the above, HRT may disclose the termination of this Agreement to any of its vendors or suppliers.

ARTICLE VI INDEMNIFICATION

- 6.1 **Indemnification by HRT.** Except as otherwise specifically provided herein, HRT shall indemnify and hold harmless PPLP and its officers, directors, agents, employees, distributors, successors and assigns from and against all Claims, actions, losses, damages, costs, expenses or other liabilities in respect of any third party Claims arising out of (a) the use, development, marketing, seeking Regulatory Approval of or distribution of the Product by HRT, (b) breach of any of HRT's material obligations under this Agreement, including HRT's representations and warranties, or (c) the willful misconduct or grossly negligent acts of HRT, or the officers, directors, employees, or agents of HRT; provided that HRT shall have no liability or indemnification obligation under this Section 6.1 arising from liabilities to third parties principally caused by the acts or omissions of PPLP.
- 6.2 **Limitation of Liability.** EXCEPT WITH RESPECT TO A BREACH OF THE CONFIDENTIALITY PROVISIONS SET FORTH IN ARTICLE VII, INDEMNIFICATION OBLIGATIONS FOR THIRD PARTY CLAIMS PURSUANT TO SECTION 6.1, AND FAILURE TO COMPLY WITH THE ASSIGNMENT PREREQUISITES PURSUANT TO SECTION 3.2, NO PARTY SHALL BE ENTITLED TO RECOVER FROM ANY OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, INDIRECT OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT.

ARTICLE VII CONFIDENTIALITY AND NONDISPARAGEMENT

- 7.1 **Confidentiality.** Except as otherwise agreed in writing between the Parties, the Parties will keep the terms of this Agreement confidential; provided, however, that either Party may disclose such terms (i) to the extent required by applicable law, (ii) to obtain Bankruptcy Court approval of the Approval Order or otherwise as may be reasonably required in connection with the confirmation or consummation of any plan of reorganization, (iii) as may be requested by any court appointed monitor of any PPLP injunction, or (iv) pursuant to any request for information from any other governmental entity or any compulsory legal process.
- 7.2 **Nondisparagement.** PPLP and HRT each agree that for a period of five (5) years from the Amended and Restated Effective Date, neither Party will disparage, portray in a negative or false light, or take any action that would lead to unfavorable publicity for the other Party or its employees or owners, whether such disparagement, portrayal, or action is made publicly or privately, in the form of opinion or otherwise and including, without limitation, in any and all interviews, verbal statements, written materials, and electronically-displayed materials; all of the above, only to the extent that such disparagement, portrayal, publicity or action relates to this Agreement, the Parties' ongoing relationship, or PPLP's funding and support for HRT's development of the Product. Neither Party shall be deemed to be in breach of this Section 7.2 if the alleged disparagement, portrayal, publicity or action by such Party is truthful and is made in

connection with legally required testimony, pleading, investigation or any legal proceeding in front of a court, an arbitration panel or any governmental agency or entity.

ARTICLE VIII COMMUNICATIONS, COOPERATION AND PRESENTATION OF RESEARCH

- 8.1 **Collaboration.** PPLP and HRT will collaborate on a public communications strategy related to HRT's development of the Product and PPLP's support thereof and will align on scheduled milestones for joint communications (e.g., press releases, social media, and statements), which may include up to four (4) opportunities per year.
- 8.2 **Presentation of Research.** If HRT intends to present research data related to the Product at a scientific forum or other public venue, it will notify PPLP not less than forty-five (45) days in advance of such event and HRT and PPLP will discuss whether and how PPLP's support of HRT and HRT's development will be referenced; provided that no such reference may be made without PPLP's prior written consent, which will not be unreasonably withheld. HRT and PPLP will also agree upon any press releases, social media releases or other announcements proposed to be made regarding such presentation.
- 8.3 **Websites and Social Media.** PPLP and HRT will continue to include information about funding and support provided by PPLP on both Parties' websites and through social media channels.

ARTICLE IX MISCELLANEOUS PROVISIONS

- 9.1 **Assignment.** HRT shall not assign this Agreement without PPLP's prior written consent, which consent shall not be unreasonably withheld, provided however, that no such consent will be required in connection with the sale or transfer of all or substantially all of HRT's assets, provided that the successor to HRT shall be (i) a not for profit organization, (ii) a benefit corporation or (iii) another entity reasonably acceptable to PPLP, and shall have assumed, in a writing delivered to PPLP, all of the duties and obligations of HRT and shall agree to make all of the representations and warranties and observe all of the covenants of Section 4.2. PPLP may assign this Agreement or all of its rights and may delegate any or all of its obligations hereunder, provided that no such assignment shall be binding and valid until and unless the assignee shall have assumed, in a writing delivered to HRT, all of the duties and obligations of PPLP; provided that any assignment by PPLP in connection with the consummation of a plan of reorganization of PPLP shall be deemed to have satisfied the requirement of the delivery of such a writing.
- 9.2 **Notices.** Any notice or other communication which shall or may be given pursuant to this Agreement shall be in writing and shall be delivered by certified mail or by facsimile transmission confirmed by certified mail, addressed to the Parties' respective addresses as set forth below:

If to HRT: Harm Reduction Therapeutics, Inc.
4800 Montgomery Lane, Suite 400
Bethesda, MD 20814
Attn: President

With a copy to: K&L Gates LLP
K&L Gates Center
210 Sixth Avenue
Pittsburgh, PA 15222-2613
Attn: Oded Green

If to PPLP: Purdue Pharma L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, Connecticut 06901
Attn: General Counsel

With a copy to: Purdue Pharma L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, Connecticut 06901
Attn: Chief Financial Officer

and

Arnold and Porter Kaye Scholer LLP
250 West 55th Street
New York, New York 10019-9710
Attn: Rory Greiss and Eric Rothman

Any Party may change its address by notice to the other Party.

- 9.3 **Further Assurances.** Each Party shall take all such steps, execute all such documents and do all such acts and things as may be reasonably required by the other Party to give effect to any of the transactions contemplated by this Agreement.
- 9.4 **Agency and Representation.** The legal relationship between the Parties shall not be construed such that any Party is deemed a partner or agent of the other Party, nor will it confer upon any Party the right or power to bind the other Party in any contract or to the performance of any obligations as to any third party. Each Party shall conduct its transactions and operations with the other as an independent contractor.
- 9.5 **Non-Waiver.** Neither the failure of any Party to enforce at any time any of the provisions of this Agreement nor the granting of any time or other indulgence shall be construed as a waiver of that provision or of the right of that Party thereafter to enforce that or any other provision.

- 9.6 **Severability.** In the event that any provision of this Agreement would be held in any jurisdiction to be invalid, prohibited or unenforceable for any reason, such provision, as to such jurisdiction, shall be ineffective, without invalidating the remaining provisions of this Agreement or affecting the validity or enforceability of such provision in any other jurisdiction. Notwithstanding the foregoing, if such provision could be more narrowly drawn so as not to be invalid, prohibited or unenforceable in such jurisdiction, it shall, as to such jurisdiction, be so narrowly drawn, without invalidating the remaining provisions of this Agreement or affecting the validity or enforceability of such provision in any other jurisdiction.
- 9.7 **Costs.** Each Party shall bear its own costs arising out of the negotiation and preparation of this Agreement.
- 9.8 **Entire Agreement.** This Agreement constitutes the entire agreement between the Parties concerning the subject matter hereof, amends and restates in its entirety the Funding Agreement and supersedes all Prior Agreements, whether written or oral, other than the Confidentiality Agreement and Right of Reference Agreement, which will remain in full force and effect. This Agreement has no effect on the Agreement dated as of June 26, 2018, by and between HRT and Mundipharma International Corporation Limited (including its related Assignment and Bill of Sale and Assignment). Upon execution of this Agreement, other than the Confidentiality Agreement and Right of Reference Agreement, the Prior Agreements no longer remain in full force and effect.
- 9.9 **Amendment.** This Agreement may not be amended except by a further written agreement duly executed by authorized representatives of the Parties.
- 9.10 **Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of the State of New York without reference to its choice of law and conflicts of law provisions.
- 9.11 **Counterparts.** This Agreement may be executed in two or more counterparts (including by facsimile or other electronic transmission), each of which shall be deemed an original, but all of which together shall constitute a single agreement.
- 9.12 **Third-Party Beneficiaries.** Except as specifically provided herein, this Agreement is not intended to confer upon any non-party any rights or remedies hereunder.
- 9.13 **Survival.** The provisions of Section 3.1 and Articles VI, VII and IX shall survive the termination of this Agreement.
- 9.14 **Force Majeure.** Each Party will be excused for delays in performing or from its failure to perform hereunder to the extent that the delays or failures result from causes beyond the reasonable control of such Party; provided that, in order to be excused from the delay or failure to perform, such Party must act diligently to remedy the cause of the delay or failure.

IN WITNESS WHEREOF, the parties have caused this Agreement to be signed by their duly authorized representatives as of the date first written above.

HARM REDUCTION THERAPEUTICS, INC.

DocuSigned by:

Michael Hufford

E92DD02873A74D2...

BY: Michael Hufford, Ph.D.

TITLE: CHIEF EXECUTIVE OFFICER

PURDUE PHARMA L.P.

By: PURDUE PHARMA INC., ITS GENERAL PARTNER

DocuSigned by:

Julie Ducharme

5F17C84E2314443...

BY:

TITLE:

Exhibit A

Market Forecast of OTC Naloxone at Cost Units										
2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	Cumulative
0	-	469,861	1,107,130	1,660,872	1,857,501	2,018,270	2,077,035	2,137,686	2,200,288	13,528,642

Exhibit B

**Blackline of Revised Form of Amended and Restated Funding Agreement Against Original
Form of A&R Funding Agreement**

AMENDED AND RESTATED FUNDING AGREEMENT

This Amended and Restated Funding Agreement (“Agreement”) is dated as of ~~[-]~~ March 22, 2022 between Harm Reduction Therapeutics, Inc., a nonstock Maryland not-for-profit corporation (“HRT”), and Purdue Pharma L.P., a Delaware limited partnership (“PPLP”). (As used herein, each of HRT and PPLP is referred to as a “Party” and collectively as the “Parties.”)

WHEREAS, the Parties previously entered into a Funding Agreement, dated as of June 25, 2020 (“Funding Agreement”);

WHEREAS, PPLP has provided funding to HRT, under the Funding Agreement, in the amount of \$6,500,000 based on HRT’s achievement of certain milestones set forth in the Funding Agreement;

WHEREAS, the Parties wish to amend and restate the Funding Agreement in its entirety;

WHEREAS, in addition to the funding provided under the Funding Agreement, PPLP has previously provided HRT funding to begin development of the Product including pursuant to prior written agreements between the Parties (the “Prior Agreements”);

WHEREAS, this Agreement is intended to supersede all Prior Agreements between the Parties, other than the Letter Agreement dated November 9, 2017 (the “Confidentiality Agreement”) and the Agreement dated as of July 29, 2019 (the “Right of Reference Agreement”);

WHEREAS, PPLP is committed to addressing opioid use disorder and is seeking partners to support and accelerate impactful initiatives and scientific discoveries;

WHEREAS, HRT is interested in developing, marketing, seeking Regulatory Approval of, and distributing solely in the Territory a single dose, over-the-counter, naloxone intranasal spray device intended to treat opioid overdoses (the “Product”);

WHEREAS, PPLP and HRT wish to enter into this Agreement pursuant to which PPLP will fund the continuation of HRT’s development work in connection with the Product with the goal of having HRT seek Regulatory Approval of the Product and ultimately for HRT to be able to provide the approved Product to first responders, government agencies, not-for-profit entities, communities and individuals (collectively, “Contemplated Product Users”), subject to the terms and conditions set forth below.

NOW THEREFORE, HRT and PPLP, intending to be legally bound, hereby agree as follows:

ARTICLE I DEFINITIONS

- 1.1 “Approval Order” means an order of the Bankruptcy Court, in form and substance reasonably acceptable to the Parties, approving PPLP’s entry into this Agreement.
- 1.2 “Bankruptcy Court” means the United States Bankruptcy Court for the Southern District of New York having jurisdiction over the Chapter 11 Cases.

- 1.3 “Chapter 11 Cases” means the bankruptcy cases filed on September 15, 2019 by PPLP and certain of its affiliates under Chapter 11 of the United States Code in the Bankruptcy Court and jointly administered under Case No. 19-23649 (RDD).
- 1.4 “Claim” means, with respect to any Person, any claim, demand, action, proceeding, judgment, damage, loss, cost, expense, or liability whatever, incurred or suffered by or brought, made, or recovered against such Person (whether or not presently ascertained, immediate, future, or contingent) arising out of or relating to the sale or use of the Product by HRT or by any holder or user of the Product that in the chain of distribution came from or through HRT.
- 1.5 “Cost” means HRT’s cost of goods sold for PPLP Funded Products (as defined in Section 2.3), on a fully absorbed basis, including general and administrative expenses, in accordance with United States generally accepted accounting principles, and any federal excise taxes and other federal, state and local taxes, as applicable.
- 1.6 “FDA” means the United States Food and Drug Administration, or any successor entity.
- 1.7 “GMP” means the then-current good manufacturing practices set forth in the quality system regulation 21 C. F. R. Part 820, governing the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use, as such practices may be updated from time to time.
- 1.8 “IND” means an Investigational New Drug Application as defined in the Federal Food, Drug and Cosmetic Act (“FD&C Act”).
- 1.9 “Milestone Event” means any of the events set forth in Section 2.2 under the column “Milestone Event.”
- 1.10 “Milestone Payment” means any of the payments set forth in Section 2.2 under the column “Milestone Payment.”
- 1.11 “NDA” means a New Drug Application as defined in the FD&C Act.
- 1.12 “Original Effective Date” means the effective date of the Funding Agreement.
- 1.13 “Person” means any natural person, corporation (including any non-profit corporation), cooperative, company, foundation, general partnership, limited partnership, limited liability company, unlimited liability company, joint venture, estate, trust, association, organization, labor union, governmental body, custodian, nominee and any other individual or entity.
- 1.14 “Product Registration” means, in relation to the Product, an NDA that has been approved by the FDA, including any amendments or supplements.

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- 1.15 “Regulatory Approval” means drug approval and all other approvals necessary for the distribution of Product in the Territory.
- 1.16 “Regulatory Authority” means any federal, state, local, municipal, provincial or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).
- 1.17 “Regulatory Materials” means regulatory applications, submissions, notifications, communications, correspondence, registrations, drug approvals or other filings made to, received from or otherwise conducted with a Regulatory Authority to develop, manufacture, market, sell or otherwise distribute Product in the Territory.
- 1.18 “RiVive” means the proposed name of 3.0 mg of the intranasal Product (as such name may be amended from time to time).
- 1.19 “Territory” means the United States of America, including its territories and possessions.
- 1.20 “Unit” means one package containing two RiVive intranasal naloxone devices.

ARTICLE II EFFECTIVENESS; FINANCIAL ASSISTANCE

- 2.1 **Effectiveness.** This Agreement shall, upon entry of the Approval Order by the Bankruptcy Court and execution and delivery by the Parties, become effective and binding upon the Parties (such date, the “Amended and Restated Effective Date”).
- 2.2 **Financial Assistance; Milestone Payments.**
- (a) HRT will use commercially reasonable efforts to develop the Product and will use the funding provided by PPLP and referenced below only for (i) the development of the Product, (ii) other related activities, and (iii) general working capital, including legal and compliance costs and expenses.
- (b) PPLP hereby agrees to provide funding to HRT in the form of Milestone Payments to encourage HRT’s continued development of the Product in the Territory, payable after the achievement of certain Milestone Events. The Milestone Payments are described below:

Milestone Event and Primary Purpose	Milestone Payment	Expected Milestone Achievement/ Expected Payment Date
Clinical study successfully demonstrates that RiVive naloxone concentrations are as high as the FDA approved comparator product (Development, drug product stability, NDA preparation, device reliability and production)	\$3,000,000	Completion date: January 31, 2022. Milestone achieved. Payment Due Date: April 1, 2022

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equipment)		
Acceptable drug product 24-month stability achieved to support targeted 24-month shelf life for commercial product (NDA preparation, pre-validation batch manufacture, sales & marketing preparations and on-going development work)	\$3,000,000	Targeted completion date: August 31, 2022 Payment Due Date: Within thirty (30) days after HRT delivers a written notice to PPLP that the applicable milestone has been met
New Drug Application for RiVive filed with the FDA (Manufacturing site readiness, partial support of commercial batch components, sales and marketing support prior to 1 st commercial shipment)	\$5,000,000	Targeted completion date: October 28 th , 2022 Payment Due Date: Within thirty (30) days after HRT delivers a written notice to PPLP that the applicable milestone has been met

The above referenced milestone achievement dates are expected dates only, are not intended to be deadlines and do not trigger any Milestone Payments (unless the Milestone Event has actually occurred). Each Milestone Payment is a one-time only payment based on the achievement of the Milestone Event; provided, that no Milestone Payment will be made unless the previously listed Milestone Event has been achieved. Promptly after HRT determines that it has achieved a Milestone Event, HRT shall provide notice thereof to PPLP in accordance with Section 9.2 hereof, which notice shall include sufficient detail of the achievement of such Milestone Event to enable PPLP to verify whether it agrees with HRT's determination. If, after receipt of the foregoing notice, PPLP agrees, reasonably and in good faith, that a Milestone Event has been achieved by HRT, PPLP shall pay the corresponding Milestone Payment to HRT within the time period set forth in the above chart after the date the Milestone Event was achieved or at such later time as HRT may request; provided, in no event will the Milestone Payment be due prior to the corresponding expected Payment Date set forth in the above chart. If PPLP does not agree that a Milestone Event has been achieved, the Parties will work in good faith to resolve any such dispute.

The aggregate amount of the Milestone Payments shall not exceed eleven million dollars (\$11,000,000). Any amounts not funded in 2022 will be funded in the subsequent year; provided, that PPLP shall in no event be required to fund any amounts after March 31, 2023, regardless of whether a Milestone Event is achieved after such date.

Notwithstanding the foregoing, (i) if HRT licenses from a third party an FDA-approved product (i.e., with a Regulatory Approval) to serve as the Product, PPLP shall not make the Milestone Payments referred to above, but the Parties will discuss in good faith any alternative funding that may be required by HRT to obtain approval for the Product (i.e., with a Regulatory Approval) to be distributed over-the-counter and (ii) if HRT receives any funding from any third party that is based on a new request or application made or submitted solely after the Original Effective Date to fund the development of the Product pre-commercialization, and such third party financing is received, such third party funding

will reduce the amount of subsequent unpaid Milestone Payments by the amount of such third party funding (with the understanding that it will not reduce any other Milestone Payment hereunder and that HRT will have no obligation to return any Milestone Payments previously paid to HRT).

2.3 Financial Assistance for HRT's Manufacture and Distribution of Product.

As part of PPLP's public health initiatives, after FDA Regulatory Approval of HRT's NDA for the Product, PPLP may provide funds to HRT to enable HRT to manufacture Units of Product ("PPLP Funded Products") so that such Units can be donated free of charge or sold at Cost to Contemplated Product Users. The current market forecast for at Cost Units is depicted on Exhibit A attached hereto.

In the event PPLP does provide funding to HRT to enable HRT to manufacture PPLP Funded Products, at least two (2) months prior to each calendar quarter HRT and PPLP will agree upon a written annual forecast of PPLP Funded Products to be manufactured and donated free of charge or sold at Cost to the Contemplated Product Users as follows:

(i) a binding forecast for the quantities of PPLP Funded Products to be manufactured and donated free of charge or sold at Cost to the Contemplated Product Users during the upcoming calendar quarter, with projected delivery dates, sizes, strengths and ultimate destinations, as well as other relevant manufacturing and delivery information. PPLP shall fund one hundred percent (100%) of the Cost of such agreed upon forecast of PPLP Funded Products;

(ii) an estimate of the quantities of PPLP Funded Products to be manufactured and donated free of charge or sold at Cost to the Contemplated Product Users during the calendar quarter following the upcoming calendar quarter. PPLP shall fund at least fifty percent (50%) of the Cost of such forecast of PPLP Funded Products; and

(iii) a non-binding estimate of the forecast of PPLP Funded Products HRT intends to manufacture and which will be donated free of charge or sold at Cost to the Contemplated Product Users for the third and fourth calendar quarters of such forecast.

Each subsequent written forecast shall update the prior estimate and include an estimate of requirements for the next additional calendar quarter, so that estimates for a rolling one- (1-) year period are provided.

For avoidance of doubt, HRT shall not be obligated to produce and deliver any PPLP Funded Product to any Contemplated Product User unless PPLP has funded the applicable verifiable Cost related thereto, sufficient time in advance, as agreed upon by the Parties, in accordance with the forecasts set forth above or otherwise (at an agreed upon rate reasonably calculated to allow HRT to diligently produce the Product). Any payments received by HRT in advance of the future donation or sale of PPLP Funded Products will be credited to the funding of the next forecasted quantities of PPLP Funded Products. Following the filing of an NDA for the Product, PPLP and HRT may further refine the forecasting provisions set forth above.

2.4 **Audit Rights.**

- (a) Commencing as of the Original Effective Date and ending on the earlier of (i) termination or expiration of this Agreement, or (ii) the third anniversary of the latest delivered Milestone Payment, PPLP shall have the right to conduct audits of HRT's data and its books and records to reasonably determine whether Milestone Events have been achieved.
- (b) Commencing as of the Original Effective Date, PPLP shall have the right to conduct audits of the books and records of HRT not more than once during each calendar year (i) until the date of Regulatory Approval of HRT's NDA for the Product, to determine that the funds provided by PPLP have been used in a manner consistent with Section 2.2 (a) and (ii) after FDA Regulatory Approval of HRT's NDA for the Product and until the termination of this Agreement, to verify HRT's Cost related to Units of Product.
- (c) PPLP may exercise the audit rights described in (a) and (b) above by providing written notice to HRT and any such audit shall be conducted during normal business hours. HRT shall make available to PPLP such accounting and other books and records, reasonably requested by PPLP to exercise its rights hereunder.

2.5 **Reports.**

At least once during each month until the last Milestone Event has been achieved, HRT shall provide a written report to PPLP regarding its progress toward developing the Product and achieving the Milestone Events, including an update on the Expected Milestone Achievement Date for each such Milestone Event. Each report will account for HRT's expenditures of funding provided by PPLP allocated among the three categories set forth in Section 2.2(a). HRT shall also report on any funding that it received from third parties in connection with the Product, promptly after it becomes aware of such funding.

ARTICLE III INTELLECTUAL PROPERTY

- 3.1 **Ownership of Data; Product Registrations.** HRT will be the sole owner of (a) all the data generated by HRT supporting development and registration of the Product, (b) the database of such data, (c) all Regulatory Approvals and Product Registrations in the Territory, and (d) all Regulatory Materials, except as may be set forth in any other agreement between the Parties.
- 3.2 **IP Assignment.** HRT and its affiliates may assign, sell, license ~~on an exclusive basis~~, or otherwise transfer any intellectual property related to the Product, only with the prior written consent of PPLP. ~~Notwithstanding the foregoing, HRT and its affiliates may non-exclusively license the underlying intellectual property of the Product or any portion thereof in the ordinary course of business, in connection with the development, testing (including clinical trials), production or manufacture of the Product, upon notice to, but without the consent of, PPLP, such consent not to be unreasonably withheld or denied.~~ Any purported assignment, sale or transfer of rights in or to any intellectual property in contravention of this Section 3.2 shall be null and void ab initio. The restrictions set forth in this Section 3.2 shall expire on ~~December 31, 2031~~ June 30, 2039. PPLP hereby consents to the grant, by HRT, of a non-exclusive license to the Producer (as defined below) related to the underlying intellectual property of the Product, for the limited purpose of producing, manufacturing and supplying the Products for HRT. "Producer" means HRT's currently contemplated producer, contract manufacturer and supplier of the Products, and any substitutes (in whole or in part) thereof.

ARTICLE IV REPRESENTATIONS, WARRANTIES AND COVENANTS

- 4.1 **Mutual Representations and Warranties.** Each Party hereby represents and warrants to the other Party as of the date hereof and as of the Original Effective Date and Amended and Restated Effective Date as follows:
- A. **Authority.** It is validly existing and in good standing or active under the laws of the jurisdiction of incorporation or organization, has the power and authority to enter into this Agreement and has taken all necessary actions on its part required to authorize the execution and delivery of this Agreement. This Agreement has been duly executed and delivered by such Party and constitutes the valid and binding obligation of such Party, enforceable against it in accordance with its terms except as enforceability may be limited by bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to or affecting creditors' rights generally and by general equitable principles. The execution, delivery and performance of this Agreement has been duly authorized by all necessary action on the part of such Party, its officers, directors, members and/or managers, as applicable.

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- B. **No Conflict.** The execution, delivery and performance of this Agreement by such Party does not, to such Party's knowledge, violate any material law or regulation or any order of any court, governmental body or administrative or other agency having authority over them. It is not currently a party to any material agreements, oral or written, that would cause it to be in breach of its obligations under this Agreement, and execution and delivery of this Agreement does not and will not conflict with, violate or breach any contractual obligations of such Party.

4.2 **HRT Representations, Warranties and Covenants.** HRT hereby further represents, warrants and covenants to PPLP that:

- A. As of the Original Effective Date, HRT is and, during the term of this Agreement will continue to be, a nonstock corporation organized under the laws of the State of Maryland. HRT shall not contemplate pecuniary gain or profit, incidental or otherwise, and no part of the net earnings of HRT shall inure to the benefit of or be distributed to any director or officer of HRT, or to any other private person, except that HRT shall be authorized and empowered to pay reasonable compensation for services rendered and to make payments and distributions in furtherance of its charitable and/or public benefit purposes.
- B. While receiving funding from PPLP under this Agreement, HRT will not participate in any lobbying activities that are prohibited by PPLP injunction(s), as delivered to HRT in writing from time to time. Advocacy by HRT before any Regulatory Authority regarding Regulatory Approval of the Product shall not be deemed to violate this Section 4.2(B).
- C. HRT will develop the Product, manufacture PPLP Funded Products, and sell or donate PPLP Funded Products, in compliance with all applicable laws, including any applicable state transparency laws and applicable guidelines such as GMP (as and to the extent applicable to the PPLP Funded Products), then-current good clinical practice standards and procedures promulgated or endorsed by the FDA (as and to the extent applicable), then-current good laboratory practice standards promulgated or endorsed by the FDA and guidelines issued by the International Council for Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (as and to the extent applicable).
- D. HRT will use commercially reasonable efforts (taking into account the applicable global and local economic, health/pandemic and market conditions, as well as availability of funding) to obtain funding from third parties for the development of the Product and to supply funding for supply readiness and launch of the Product.
- E. If HRT is no longer organized for charitable or public benefit purposes or no longer otherwise qualifies as any of (i) a non-stock corporation, (ii) a benefit corporation, or (iii) another form of entity acceptable to PPLP, (x) HRT will provide written notice to PPLP that it is no longer so organized or no longer so qualifies, (y) HRT will repay to PPLP all amounts provided to it by PPLP under this Agreement, including all cash funding provided by PPLP to HRT under the Prior Agreements,

no later than one (1) year after written request for such repayment is made by PPLP and (z) in PPLP's sole discretion but subject to HRT's receipt of any necessary governmental or regulatory approvals and compliance with applicable laws, PPLP will be entitled to forty percent (40%) of all of the equity interests in HRT. For clarity, denial of HRT's application for treatment as a tax exempt entity under Section 501(c)(3) of the Internal Revenue Code of 1986, as amended, by itself, will not mean that HRT no longer qualifies as an entity described above.

ARTICLE V TERM AND TERMINATION

- 5.1 **Term.** This Agreement shall become effective on the Amended and Restated Effective Date and shall remain in effect until terminated pursuant to Sections 5.2, 5.3 or 5.4.
- 5.2 **Termination for Material Breach.** Either Party shall have the right to terminate this Agreement in the event that the other Party commits a material breach of this Agreement by giving written notice of such breach to the breaching Party. Termination shall be effective ninety (90) days after the giving of such notice unless the breaching Party has remedied the breach within such ninety (90) day period.
- 5.3 **Termination for Bankruptcy or Change of Status.** PPLP may terminate this Agreement upon notice to HRT if HRT becomes insolvent, makes any assignment for the benefit of its creditors, is placed in receivership, liquidation or bankruptcy or if it is no longer organized for charitable, or public benefit purposes or no longer otherwise qualifies as any of (i) a non-stock corporation, (ii) a benefit corporation, or (iii) another form of entity acceptable to PPLP. PPLP's right to terminate under this Section 5.3 is in addition to any of its rights under Section 4.2 E. of this Agreement.
- 5.4 **Termination by PPLP.** PPLP may terminate this Agreement, upon (x) fifteen (15) days' prior written notice if HRT has not achieved a Milestone Event set forth in Section 2.2 within one hundred eighty (180) days of the Targeted Completion Date set forth with respect to such Milestone Event or (y) sixty (60) days' prior written notice, if HRT has stopped using commercially reasonable efforts to develop Product in the Territory (during which sixty (60)-day period HRT may resume using such efforts and upon PPLP's reasonable satisfaction that such efforts have resumed such notice shall be withdrawn).
- 5.5 **Publicity Upon Termination.** If either Party terminates this Agreement for any reason, the Parties will agree upon the wording of any public announcement of such termination and, if the Parties are unable to reach such agreement, neither Party shall release any public announcement relating to such termination without the other Party's written consent. Following any termination of this Agreement, HRT will not make any public statements about this Agreement, the circumstances surrounding the termination or the relationship between the Parties without the prior written consent of PPLP, except for any such statements required pursuant to legal process. PPLP will give HRT prior written notice of any statement it proposes to make following such termination and, except for statements made pursuant to legal process, will take into consideration any comments HRT may have

with respect to such statements. Notwithstanding the above, HRT may disclose the termination of this Agreement to any of its vendors or suppliers.

ARTICLE VI INDEMNIFICATION

- 6.1 **Indemnification by HRT.** Except as otherwise specifically provided herein, HRT shall indemnify and hold harmless PPLP and its officers, directors, agents, employees, distributors, successors and assigns from and against all Claims, actions, losses, damages, costs, expenses or other liabilities in respect of any third party Claims arising out of (a) the use, development, marketing, seeking Regulatory Approval of or distribution of the Product by HRT, (b) breach of any of HRT's material obligations under this Agreement, including HRT's representations and warranties, or (c) the willful misconduct or grossly negligent acts of HRT, or the officers, directors, employees, or agents of HRT; provided that HRT shall have no liability or indemnification obligation under this Section 6.1 arising from liabilities to third parties principally caused by the acts or omissions of PPLP.
- 6.2 **Limitation of Liability.** EXCEPT WITH RESPECT TO A BREACH OF THE CONFIDENTIALITY PROVISIONS SET FORTH IN ARTICLE VII, INDEMNIFICATION OBLIGATIONS FOR THIRD PARTY CLAIMS PURSUANT TO SECTION 6.1, AND FAILURE TO COMPLY WITH THE ASSIGNMENT PREREQUISITES PURSUANT TO SECTION 3.2, NO PARTY SHALL BE ENTITLED TO RECOVER FROM ANY OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, INDIRECT OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT.

ARTICLE VII CONFIDENTIALITY AND NONDISPARAGEMENT

- 7.1 **Confidentiality.** Except as otherwise agreed in writing between the Parties, the Parties will keep the terms of this Agreement confidential; provided, however, that either Party may disclose such terms (i) to the extent required by applicable law, (ii) to obtain Bankruptcy Court approval of the Approval Order or otherwise as may be reasonably required in connection with the confirmation or consummation of any plan of reorganization, (iii) as may be requested by any court appointed monitor of any PPLP injunction, or (iv) pursuant to any request for information from any other governmental entity or any compulsory legal process.
- 7.2 **Nondisparagement.** PPLP and HRT each agree that for a period of five (5) years from the Amended and Restated Effective Date, neither Party will disparage, portray in a negative or false light, or take any action that would lead to unfavorable publicity for the other Party or its employees or owners, whether such disparagement, portrayal, or action is made publicly or privately, in the form of opinion or otherwise and including, without limitation, in any and all interviews, verbal statements, written materials, and electronically-displayed materials; all of the above, only to the extent that such disparagement, portrayal, publicity or action relates to this Agreement, the Parties'

on-going relationship, or PPLP's funding and support for HRT's development of the Product. Neither Party shall be deemed to be in breach of this Section 7.2 if the alleged disparagement, portrayal, publicity or action by such Party is truthful and is made in connection with legally required testimony, pleading, investigation or any legal proceeding in front of a court, an arbitration panel or any governmental agency or entity.

ARTICLE VIII COMMUNICATIONS, COOPERATION AND PRESENTATION OF RESEARCH

- 8.1 **Collaboration.** PPLP and HRT will collaborate on a public communications strategy related to HRT's development of the Product and PPLP's support thereof and will align on scheduled milestones for joint communications (e.g., press releases, social media, and statements), which may include up to four (4) opportunities per year.
- 8.2 **Presentation of Research.** If HRT intends to present research data related to the Product at a scientific forum or other public venue, it will notify PPLP not less than forty-five (45) days in advance of such event and HRT and PPLP will discuss whether and how PPLP's support of HRT and HRT's development will be referenced; provided that no such reference may be made without PPLP's prior written consent, which will not be unreasonably withheld. HRT and PPLP will also agree upon any press releases, social media releases or other announcements proposed to be made regarding such presentation.
- 8.3 **Websites and Social Media.** PPLP and HRT will continue to include information about funding and support provided by PPLP on both Parties' websites and through social media channels.

ARTICLE IX MISCELLANEOUS PROVISIONS

- 9.1 **Assignment.** HRT shall not assign this Agreement without PPLP's prior written consent, which consent shall not be unreasonably withheld, provided however, that no such consent will be required in connection with the sale or transfer of all or substantially all of HRT's assets, provided that the successor to HRT shall be (i) a not for profit organization, (ii) a benefit corporation or (iii) another entity reasonably acceptable to PPLP, and shall have assumed, in a writing delivered to PPLP, all of the duties and obligations of HRT and shall agree to make all of the representations and warranties and observe all of the covenants of Section 4.2. PPLP may assign this Agreement or all of its rights and may delegate any or all of its obligations hereunder, provided that no such assignment shall be binding and valid until and unless the assignee shall have assumed, in a writing delivered to HRT, all of the duties and obligations of PPLP; provided that any assignment by PPLP in connection with the consummation of a plan of reorganization of PPLP shall be deemed to have satisfied the requirement of the delivery of such a writing.
- 9.2 **Notices.** Any notice or other communication which shall or may be given pursuant to this Agreement shall be in writing and shall be delivered by certified mail or by facsimile

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transmission confirmed by certified mail, addressed to the Parties' respective addresses as set forth below:

If to HRT: Harm Reduction Therapeutics, Inc.
4800 Montgomery Lane, Suite 400
Bethesda, MD 20814
Attn: President

With a copy to: K&L Gates LLP
K&L Gates Center
210 Sixth Avenue
Pittsburgh, PA 15222-2613
Attn: Oded Green

If to PPLP: Purdue Pharma L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, Connecticut 06901
Attn: General Counsel

With a copy to: Purdue Pharma L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, Connecticut 06901
Attn: Chief Financial Officer

and

Arnold and Porter Kaye Scholer LLP
250 West 55th Street
New York, New York 10019-9710
Attn: Rory Greiss and Eric Rothman

Any Party may change its address by notice to the other Party.

- 9.3 **Further Assurances.** Each Party shall take all such steps, execute all such documents and do all such acts and things as may be reasonably required by the other Party to give effect to any of the transactions contemplated by this Agreement.
- 9.4 **Agency and Representation.** The legal relationship between the Parties shall not be construed such that any Party is deemed a partner or agent of the other Party, nor will it confer upon any Party the right or power to bind the other Party in any contract or to the performance of any obligations as to any third party. Each Party shall conduct its transactions and operations with the other as an independent contractor.
- 9.5 **Non-Waiver.** Neither the failure of any Party to enforce at any time any of the provisions of this Agreement nor the granting of any time or other indulgence shall be construed as a

waiver of that provision or of the right of that Party thereafter to enforce that or any other provision.

- 9.6 **Severability.** In the event that any provision of this Agreement would be held in any jurisdiction to be invalid, prohibited or unenforceable for any reason, such provision, as to such jurisdiction, shall be ineffective, without invalidating the remaining provisions of this Agreement or affecting the validity or enforceability of such provision in any other jurisdiction. Notwithstanding the foregoing, if such provision could be more narrowly drawn so as not to be invalid, prohibited or unenforceable in such jurisdiction, it shall, as to such jurisdiction, be so narrowly drawn, without invalidating the remaining provisions of this Agreement or affecting the validity or enforceability of such provision in any other jurisdiction.
- 9.7 **Costs.** Each Party shall bear its own costs arising out of the negotiation and preparation of this Agreement.
- 9.8 **Entire Agreement.** This Agreement constitutes the entire agreement between the Parties concerning the subject matter hereof, amends and restates in its entirety the Funding Agreement and supersedes all Prior Agreements, whether written or oral, other than the Confidentiality Agreement and Right of Reference Agreement, which will remain in full force and effect. This Agreement has no effect on the Agreement dated as of June 26, 2018, by and between HRT and Mundipharma International Corporation Limited (including its related Assignment and Bill of Sale and Assignment). Upon execution of this Agreement, other than the Confidentiality Agreement and Right of Reference Agreement, the Prior Agreements no longer remain in full force and effect.
- 9.9 **Amendment.** This Agreement may not be amended except by a further written agreement duly executed by authorized representatives of the Parties.
- 9.10 **Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of the State of New York without reference to its choice of law and conflicts of law provisions.
- 9.11 **Counterparts.** This Agreement may be executed in two or more counterparts (including by facsimile or other electronic transmission), each of which shall be deemed an original, but all of which together shall constitute a single agreement.
- 9.12 **Third-Party Beneficiaries.** Except as specifically provided herein, this Agreement is not intended to confer upon any non-party any rights or remedies hereunder.
- 9.13 **Survival.** The provisions of Section 3.1 and Articles VI, VII and IX shall survive the termination of this Agreement.
- 9.14 **Force Majeure.** Each Party will be excused for delays in performing or from its failure to perform hereunder to the extent that the delays or failures result from causes beyond the reasonable control of such Party; provided that, in order to be excused from the delay or

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failure to perform, such Party much act diligently to remedy the cause of the delay or failure.

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IN WITNESS WHEREOF, the parties have caused this Agreement to be signed by their duly authorized representatives as of the date first written above.

HARM REDUCTION THERAPEUTICS, INC.

BY: Michael Hufford, Ph.D.
TITLE: CHIEF EXECUTIVE OFFICER

PURDUE PHARMA L.P.

By: PURDUE PHARMA INC., ITS GENERAL PARTNER

BY:
TITLE:

~~A&P Draft 3/2/22~~

Exhibit A

Market Forecast of OTC Naloxone at Cost Units										
2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	Cumulative
0	-	469,861	1,107,130	1,660,872	1,857,501	2,018,270	2,077,035	2,137,686	2,200,288	13,528,642